4

Food Safety Risk Management

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1. Introduction

It is a principal aim of governments to assure the safety of societies in all sectors. In the food field, safety has been dealt with for a long time by making decisions in an empirical manner. Recently, risk management has been appointed as the formal scientific-based approach to address food safety issues.

From a global perspective, food safety risk management can be described *"as the process of weighting control alternatives by government (and international standard-setting bodies) in consultation with interested stakeholders, taking into account scientific information on risks to consumers as well as other relevant inputs (e.g. economics, technical feasibility, societal preferences), and choosing and implementing food safety measures as appropriate"* (Food Agriculture Organization/World Health Organization [FAO/WHO], 2006b). Indeed, governments must make decisions, whose effects are especially noted during food crises. Nevertheless, other stakeholders should also manage food risks, for example, at manufacture or consumer level. Nowadays, manufacturers and other operators involved in the food chain are aware of the importance of producing and assuring food safety, as well as the devastating consequences of supplying contaminated food products. However, at consumer level, the relevance of consumer´s hygiene practices in the home may not always be evident in order to avoid foodborne conditions.

Food safety risk management should be based on risk assessment, as proposed by the Regulation (EC) No. 178/2002 of 28 January 2002, *laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*. Currently, risk assessment is being gradually introduced at governmental level as a systematic practice. In the case of manufacturers and other food business operators, only big food enterprises have adopted risk assessment procedures; risk management in medium and small food companies is based on the implementation of Hazard Analysis and Critical Control Point (HACCP) systems, which is in fact compulsory. Hygiene practices in homes are out of the control of Health Authorities; nevertheless, for example, a risk management option mandated by governments may consist of developing educational programs which could enhance a positive attitude among consumers towards a more hygienic preparation of foods.

Food safety risk management has been proved to be useful in making science-based decisions. In this chapter, food safety risk management is addressed from various perspectives, together with management metrics to facilitate its implementation. Also, a review of risk assessment is included. A promising future can be envisaged for food safety risk management activities.

2. Perception of risk

Any attempt to manage risk begs the question: 'What is risk?' The dominant conception views risk as 'the chance of injury, damage, or loss' (Webster, 1983). The probabilities and consequences of adverse events are assumed to be produced by physical and natural processes in ways that can be objectively quantified by risk assessment. Much social science analysis rejects this notion, arguing instead that risk is inherently subjective (Pidgeon et al., 1992; Slovic, 1992; Wynne, 1992). In this view, risk does not exist "out there', independent of our minds and cultures, waiting to be measured. Instead, human beings have invented the concept *risk* to help them understand and cope with the dangers and uncertainties of life. Although these dangers are real, there is no such thing as 'real risk' or 'objective risk'. The nuclear engineer's probabilistic risk estimate for a nuclear accident or the toxicologist's quantitative estimate of a chemical's carcinogenic risk are both based on theoretical models, whose structure is subjective and assumption-laden, and whose inputs are dependent on judgment. As we shall see, nonscientists have their own models, assumptions, and subjective assessment techniques (intuitive risk assessments), which are sometimes very different from the scientists' models.

Acceptability of risk	
More if:	Less if:
Voluntary	Involuntary
Natural	Artificial
Familiar	Unfamiliar
Fair	Unfair
No dread	Dreaded
Trustworthy sources	Untrustworthy
Good process	Poor process

Table 1. The acceptability of risk varies depending on features that affect our perception of risk. (Trautman, 2001).

Not only are there differences in people, in the way they approach risks, but there are also dramatic differences in risks. Table 1 lists some perceptual features of risk that reflect a risk´s acceptability. Risks are more likely to be accepted if they have more of the features shown on the left in Table 1, e.g. if they are voluntary or familiar. So driving a car or even smoking cigarettes are readily accepted risks. Increased controversy surrounds those risks that have more features on the right, perhaps genetically modified foods or hormones in beef. It is probable that the communication gap between scientists and the public is only accentuated when several of these right-side features are in play.

Recently, the European Commission et al. (2010) has published a special Eurobarometer 354 report called “Food-related risks”. The European Food Safety Authority (EFSA) surveyed consumers across Europe about how their views on food-related risks have evolved since an earlier survey carried out in 2005 (European Commission et al., 2005, as cited in European Commission et al., 2010). It was conducted through face-to-face interviews with consumers in their mother tongue from 9 to 30 June 2010. With regards to the public perception of food and food-related risks the survey shows that the majority of respondents associate food and eating with pleasure, such as selecting fresh and tasty foods (58%) and with enjoyment of meals with friends and family (54%). Food safety (37%) is less commonly associated with

food and eating as such. Similarly, in the context of other potential risks which are likely to affect them personally, the economic crisis (20%) and environmental pollution (18%) are viewed by more respondents as risks that are much more likely to affect their lives than food-related problems (11%). When it comes to public concerns about food-related risks, the survey shows that there is no single, widespread concern mentioned spontaneously by a majority of respondents; 19% of citizens spontaneously cite chemicals, pesticides and other substances as their major concern. This concern is confirmed by prompted responses: when offered a list of possible issues associated with food, 3 out of 10 Europeans mention chemical residues from pesticides (31%), antibiotics (30%) and pollutants such as mercury and dioxins (29%), together with cloning animals for food products (30%), as risks to be "very worried" about; fewer citizens are "very worried" about health and nutrition risks like putting on weight (15%) or not having a healthy / balanced diet (15%). In terms of personal effectiveness to avoid food-related risks, EFSA found that EU citizens feel the most confident about being able to personally take steps to avoid diet and health-related issues (e.g. high fat intakes and heart disease) and bacterial contamination (e.g. salmonella in eggs); a more divided opinion is found with regard to possible risks from animal infections or diseases which could be transmitted to humans, as a larger proportion of respondents (52%) claims not to be confident in avoiding these risks; citizens feel less confident in being able to personally deal with possible problems of chemical contamination (<40%) and new technologies (<30%). With this information, one could relate these numbers with the facts showed in Table 1. For instance, campylobacteriosis is the most commonly reported zoonosis in the European Union, with 198,252 confirmed human cases in 2009 (European Food Safety Authority [EFSA] & European Centre for Disease Prevention and Control [ECDC], 2011). At the same level, the harmful consumption of alcohol is estimated to be responsible for approximately 195.000 deaths a year in the EU due to e.g. accidents, liver disease, cancers, etc. However, the harmful consumption of alcohol, which is a voluntary act and perceived as not dreaded probably due to its popularity, is underestimated by the general population, and in fact, is not included as a food-related risk in the above survey.

Slovic (1998) supported the contexualist conception of risk, which is conceived as a game. Games have time limits, rules of play, opponents, criteria for winning or losing, and so on, but none of these attributes is essential to the concept of a game, nor are any of them characteristic of all games. Similarly, a contextualist view of risk assumes that risks are characterized by some combination of attributes such as voluntariness, probability, intentionality, or equity, but that none of these attributes are essential. The bottom line is that, just as there is no universal set of rules for games, there is no universal set of characteristics for describing risk. The characterization must depend on which risk game is being played.

Often referred to as a risk management options assessment, this is the process by which different options for controlling a hazard to an "appropriate level of protection" (ALOP) are evaluated and compared. This is typically done by developing a risk assessment model that establishes mathematically the various factors that contribute to the current level of risk associated with a product/pathogen pair. Once this model is established, the model is augmented with additional parameters representing the different control strategies being considered (Buchanan, 2002).

To make decisions wisely, individuals need to understand the risks and the benefits associated with alternative courses of action. They also need to understand the limits to their

own knowledge and the limits to the advice proffered by various experts (Fischhoff et al., 1993). Some of the key questions that have to be asked when considering an optimal risk management option are: to whom it is optimal and what criteria are used to make that determination. Buchanan (2002) illustrated this with a hypothetical example. Let's consider an instance where is it necessary to achieve a reduction of pathogens on the surface of citrus fruit. In an industrialized country where labor costs are high, the use of advanced, high-speed steam surface pasteurization technologies may be the optimal system for achieving the desired reduction. However, in a developing country where labor costs are low but capital costs are high, it may be more effective to hand wash the fruit in an appropriate sanitizing solution. Thus, if the criterion for what constitutes optimal is minimal labor cost and speed then the former is optimal whereas if the criterion were minimization of capital expenditures and full employment, then the latter would be the desired approach. "Optimal", like beauty, is in the eyes of the beholder. Buchanan (2002) conceived risk assessment options assessments as a combination of two processes: risk management and assessment. Risk managers have a general idea of the degree of public health protection they are trying to achieve. Risk assessors then examine the impacts of different control options and approaches, providing the risk managers with data that allows them to more objectively evaluate proposed options. The risk managers then provide alternative management options to be evaluated. This iterative process continues until one or more risk management options achieving the desired level of protection are identified.

Risk perception and risk communication are strongly related, the former being markedly influenced by the latter. Risk communication should always have an objective, i.e. an expected attitude by the public. Usually, such an objective is set by risk managers. Some of the key points for successful risk communication are as follows (Trautman, 2001):

- Early inclusion of major stakeholders in the risk evaluation process is best. It helps avoid the appearance of trying to hide something, provides transparency, and may help identify potential pitfalls.
- Being open, honest, sincere and appreciative of other views.
- Recognizing biases and differences that are not likely to change (or only slowly), but must be expressed as part of the process.
- Finally, enlisting professional help for risk communication techniques.

3. Producer´s and consumer´s risk

Food producers and wholesalers/retailers´ efforts are focused on earning money by selling their products, primarily. There are many factors which can influence the volume of sales: the dependence of quality/quantity of the product on weather, governmental policy such as economic support or marketing of a food sector, diet fashion, complying with new legislation (e.g. on emerging risks) or food crisis.

Nowadays, consumers expect high quality from a food (frequently associated with freshness), pleasure, convenience, good price-quality balance, reasonable *consume-by-date* margins, and of course, safety. Usually, the safety of a product on the market is taken for granted, and in fact, consumers do not usually make their choice based on safety, but rather on other issues. In fact, the EU survey mentioned previously (European Commission et al., 2010) revealed that the majority of respondents associate food and eating with pleasure, such as selecting fresh and tasty foods (58%) and with enjoyment of meals with friends and family (54%); food safety (37%) was less commonly associated with food and eating as such.

Nevertheless, both producers and wholesalers/retailers do know that the safety of a food product is basic, and the consequences of unsafe food in the market could be devastating, consumers being the most-harmed stakeholders.

Todd (1989) estimated the economic impact of the acute bacterial food-borne disease in Canada and United States. Medical costs and lost income were easier to determine than losses to food companies, legal awards and settlements, value of lost leisure time, pain, grief, suffering and death. The evaluation of costs at the national level for Canada and the United States based on all available costs for 61 incidents showed that company losses and legal action are much higher than medical/hospitalization expenses, lost income or investigational costs. It was reckoned that on an annual basis an estimated 1 million cases of acute bacterial food-borne illness in Canada cost nearly after $1.1 billion and 5.5 million cases in the United States cost nearly $7 billion. The value of deaths was a major contributor to the overall costs especially for diseases like listeriosis, salmonellosis, *Vibrio* infections, and haemorrhagic colitis. Nowadays, food companies are responsible for the safety of their products in accordance to food hygiene legislation, irrespective of the official inspection. This means that, when an outbreak or an individual case is reported, legal responsibility inevitably falls on food companies.

In food microbiology, producer´s and consumer´s risks are those derived from sampling lots. It is not feasible to analyze all units of a lot (by destructive analysis techniques), so a sampling scheme must necessarily be designed for all hazards indentified in a food. Microbiological criteria applied for different foods and hazards should include a sampling plan. For example, the EC Regulation No. 2073/2005 *on microbiological criteria for foodstuffs*, establishes for *Salmonella* in different meat products a sampling plan consisting of analyzing 5 samples, from which none may exceed the microbiological limit established. When a lot is sampled, a probability of accepting "good" or "bad" lots is associated. What is more, a probability of accepting a lot when it is actually "bad" and a probability of rejecting a lot when it is actually "good" is also associated. These probabilities are the so-called consumer´s risk and producer´s risk, respectively. Table 2 shows the different sampling-based decisions.

In general, risk management at consumer level includes important issues such as good hygiene practices at home, proper heating of foods or adequate refrigerated storage of chilled foods. Risk management at producer/wholesaler/retailer´s level include a wide range of aspects such us the application of Good Manufacturing Practices, Good Hygiene Practices or the correct implementation of Hazard Analysis and Critical Control Point systems.

		Hygiene quality of a lot	
		"Good"	"Bad"
Hygiene quality detected at sampling	"Good"	Acceptance of a lot: right decision	Acceptance of a lot: wrong decision (consumer´s risk)
	"Bad"	Rejection of a lot: wrong decision (producer´s risk)	Rejection of a lot: right decision

Table 2. Decisions made at sampling of food lots.

4. Management measures to reduce risks throughout the food chain

Optimization of food control measures in terms of efficiency, effectiveness, technological feasibility and practicality at selected points throughout the food chain is the generalized goal of food businesses.

Food safety and its management has been a matter of concern to humans since the dawn of history. FAO/WHO (n.d.) described the traces of the development of the food control from Ancient History, the Middle Ages and the Industrial Revolution until the 19th and 20th centuries. Many rules and recommendations advocated in religious or historical texts are evidence of the concern to protect people against food-borne diseases and food adulteration. Modern countries have traditionally attempted to improve food safety by setting microbiological criteria for raw or for finished processed products. However, the frequency and extent of sampling used in traditional food testing programs may not provide a high degree of consumer protection.

In the 1960s, the United States Army and the United States National Aeronautics and Space Administration (NASA) developed a system to guarantee the safety of the foods that astronauts would consume in space based on prevention and not on end-product inspection and testing, from which emerged the Hazard Analysis Critical Control Points (HACCP) concept. HACCP emphasizes the control of the process as early as possible in the processing system by using operator control and/or continuous monitoring techniques at critical control points. The HACCP system can be applied throughout the food chain, from the primary producer to final consumer. The use of HACCP principles in the promulgation of regulations for low-acid canned food was completed in 1974 by the United States Food and Drug Administration (US-FDA). In the early 1980s, the HACCP approach was adopted by other major food companies and the experiences gained indicate that application of HACCP systems leads to more efficient prevention of food-borne diseases (International Commission of Microbiological Specifications for Foods [ICMSF], 1988).

Recognizing the importance of HACCP to food control, the US-FDA published a guidelines for Hazard Analysis Critical and Critical Control Point Principles and Application (US-FDA, 1997) defining HACCP as "a scientific, rational and systematic approach to the identification, evaluation, and control of food safety hazards". With this system, food safety control is integrated into the design of the process rather than the ineffective system of end-product testing. Therefore, it provides a preventive and thus a cost-effective approach to food safety. While it was originally developed to ensure microbiological safety of foodstuffs, it has been further broadened to include chemical and physical hazards in foods. (FAO/WHO, 1997a).

Sometimes a level of microbiological criteria stricter than the international level for foods in trade (based on Codex recommendations) imposed by national governments for different foods have been viewed by other countries as barriers to international trade. Because of this, more than 100 countries have signed the General Agreement on Tariffs and Trade (GATT), and "Sanitary and Phytosanitary Agreement" (SPS Agreement) of the World Trade Organization (WTO). This agreement states that, although each country has the sovereign right to decide on the degree of protection it wishes for its citizens, levels of criteria demanded for imported food must be based on scientific evidence, consideration of risk and societal issues. It also established that a country must not ask for a higher degree of safety for goods than it does for goods produced in its own country. The work of Codex through its standards, guidelines and recommendations, is recognized as the reference or 'yard stick'

for national requirements in food safety and has played an important role in facilitating international trade. (FAO/WHO, 1997a).

In Europe, the Regulation (EC) No. 178/2002, *laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*, incorporated Risk Analysis as a tool to provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health. Also, several Regulations force the implementation of HACCP system by food business operators, based on Risk Analysis criteria, and the adequate establishment of official control systems (Regulation (EC) No. 852/2004; Regulation (EC) No. 853/2004; Regulation (EC) No. 854/2004; Regulation (EC) No. 2074/2005).

The HACCP concept has provided great improvements in the production of safe foods. The goal of HACCP is to focus on the hazards in a particular food commodity that are reasonably likely to affect public health if left uncontrolled, and to design food products, processing, commercialization, preparation and use conditions that control those hazards. HACCP involves an assessment of hazards in a particular production sequence and defines steps where control measures that are critical for the safety of a product should be taken. Also, it states limits, monitoring procedures and corrective actions. To be successful, HACCP needs to build on a prerequisite programs and good practices such as good agricultural practices (GAPs), good manufacturing practices (GMPs) and good hygienic practices (GHPs), which minimize the occurrence of hazards in the product and the production environment (ICMSF, 2005). The main elements of the HACCP system are: a) identify potential hazards; b) determine the Critical Control Points (CCPs); c) establish the criteria that must be met to ensure that a CCP is under control; d) establish a monitoring system; e) establish the corrective action when CCP is out of control; f) establish procedures for verification; and g) establish documentation and record-keeping.

An ongoing assessment following the implementation of a HACCP system can be achieved at two levels; with internal audits carried out by those responsible for the system or by independent external audits. In HACCP and food safety there are several standards from a variety of sources such as legislative standards, national or international standards like International Organization for Standardization (ISO), or standards from customer–driven expert groups or food industry sectors. When standards are verified by a professional external audit and certification, the effectiveness of food safety programs can be demonstrated. Within certification, we can mention as examples the British Retail Consortium Global Standard (BRC), Global Food Safety Initiative (GFSI), ISO 22000:2005 "Food Safety Management Systems- Requirements for any organization in the food chain" and Dutch HACCP–code (Wallace et al., 2011).

Risk Management can be defined as the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. The report elaborated by FAO/WHO (1997b) considers 8 general principles of food safety risk management. The first principle states that risk management should follow a structured approach which is: risk assessment, risk management option assessment, implementation of management decision, and monitoring and review. The second principles highlights that the protection of human health should be the primary consideration in risk management decisions and arbitrary or unjustified differences in the risk levels should be avoided. The third principle deals with

risk management decisions and points out that practices should be transparent, that is to say, they should include the identification and systematic documentation of all elements of the risk management process including decision-making, so that the rationale is transparent to all interested parties. The fourth principle states that the determination of risk assessment policy should be included as a specific component of risk management. The fifth principle underlines the functional separating of risk management and risk assessment which ensures the scientific integrity. The sixth principle reminds us to take into account the uncertainty of the risk assessment in decision-making. The seventh principle states that risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process. The last principle proposes that risk management should be a continuing process that includes all newly generated data in the evaluation and review of risk management decisions. Monitoring and other activities will likely be necessary to carry out the review effectively.

Almost all the progress in the development of HACCP and other standards like effective food safety management programs and their global acceptance and use has been accomplished by the voluntary efforts of global food companies. Involvement of all stakeholders in food safety issues is crucial in order to assure food safety in our rapidly changing global food market. We need more knowledge throughout the food chain, common standards and science-based regulations, and a global infrastructure to provide global strategy and oversight (Wallace et al., 2011).

5. Risk assessment in foods

In the food safety field, the performance of Microbiological Risk Assessment (MRA) methodology has been developed as a standardized approach to integrate and evaluate information from diverse sources concerning the origin and fate of pathogens in the food chain and to determine the magnitude of public health risks. The SPS Agreement of the WTO recognized the necessity of scientific basis for evaluating food safety. Based on this consideration, principles and guidelines for food safety risk analysis were defined by the Codex Committee on Food Hygiene (FAO/WHO, 1995).

5.1 General principles for conducting MRA

The principles and guidelines for the conduct of MRA are described in Codex Alimentarius (Codex Alimentarius Commission [CAC], 1999). A formal MRA consists of four steps:

i. Hazard identification;
ii. Hazard characterization;
iii. Exposure assessment; and
iv. Risk characterization.

The definition of each step as well as their relationships are described in Figure 1.

The general principles for the conduct of MRA (CAC, 1999) can be summarized as follows:

- MRA should be soundly based upon science.
- There should be a functional separation between risk assessment and risk management.
- MRA should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment, and risk characterization.
- MRA should clearly state the purpose of the exercise, including the form of risk estimate that will be the output.

- The conduct of MRA should be transparent.
- Any constraints that impact on the risk assessment such as cost, resources or time, should be identified and their possible consequences described.
- The risk estimate should contain a description of uncertainty and where the uncertainty arose during the risk assessment process.
- Data should be such that uncertainty in the risk estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the risk estimate is minimized.
- MRA should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.
- Wherever possible, risk estimates should be reassessed over time by comparison with independent human illness data.
- MRA may need reevaluation, as new relevant information becomes available.

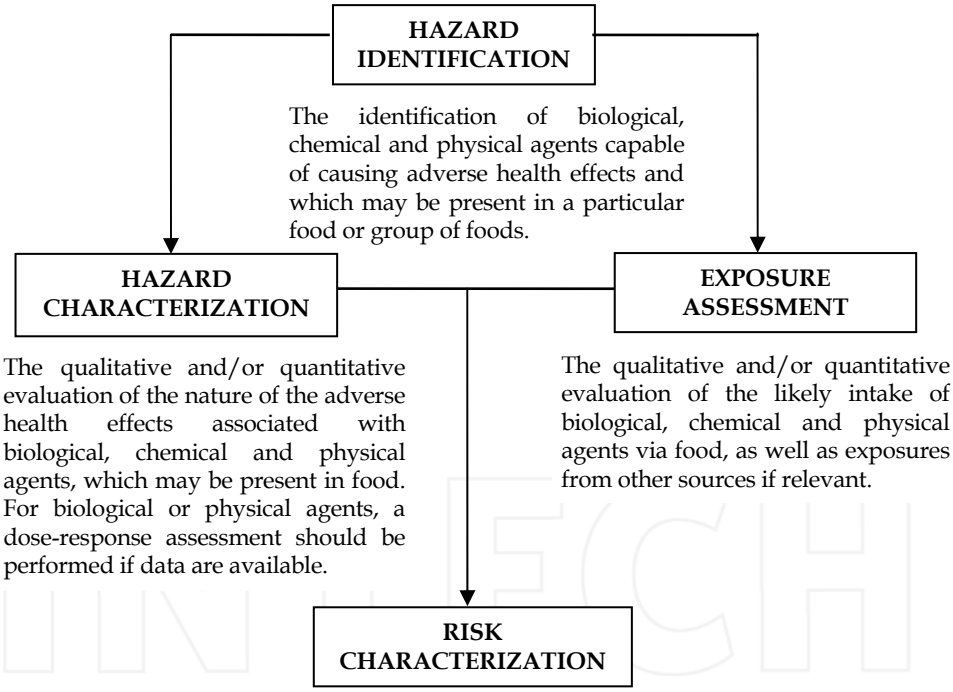

Fig. 1. Scheme of the four steps of MRA. Adapted from FAO/WHO (2006a).

These principles highlight the importance of developing a systematic and scientific methodology in order to serve as main guidance for decision-making process in the food safety field.

5.2 Uses of risk assessment outputs

Some of the final uses of risk assessment outputs are:

- Characterization of the most important factors influencing the risk of hazards identified in the food chain.
- Identification of strategies for risk mitigation.
- Establishment of guidelines for ranking priorities to be addressed in public health and food safety programs.

With regard to this, it is worth mentioning that risk assessment of foods is part of the risk analysis framework. The Regulation (EC) No. 178/2002 *laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety* states in its Article 17 that *"Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis – risk assessment, risk management, and risk communication – provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health."*.

For risk assessment issues, the World Health Organization (WHO) and the Food and Agricultural Organization of the United Nations (FAO) are coordinated by the establishment of the Joint Expert Meetings on Microbiological Risk Assessment. This group has initiated a process to produce guidelines on four steps of the MRA process and has produced several international risk assessments, based mainly on a combination of modules developed for national risk assessments. Since the mid-90s, several MRA have been developed for different food/risk combinations. Some of the main purposes of conducting MRA are focused on providing a response to questions such as:

- Which foods pose a higher risk for the selected pathogen?
- Which interventions can effectively control the pathogen?
- How can corrective measures be implemented in food industries?
- Which is the effectiveness of testing and sanitation of food contact surfaces on mitigating product contamination and reducing the subsequent risk of illness?
- How effective are alternative pre- and post-processing interventions in mitigating product contamination and reducing the subsequent risk of illness?

The most important significance of MRA (even more than the estimation of the human health risk) is that it allows an "a priori" assessment of the effect of intervention measures throughout the whole food chain, or combinations of intervention measures, on public health (Havelaar et al., 2008). Thus, risk managers can request the development of MRA in order to provide a clear scientific methodology to support decisions regarding food safety and apply control measures with, as ultimate objective, food safety assurance. In this sense, it is important to be sure that a clear mandate is transmitted to risk assessors and that the MRA satisfies the risk manager actual needs. Once established, the MRA should be further examined by the scientific community and, if necessary, by the general public.

The results obtained in the MRA may be well described for their utilization by risk managers in order to adequately select the most convenient options to improve food safety. In fact, risk assessment may also involve judgments and choices that are not entirely

scientific, and risk managers need a sound understanding of scientific approaches used by risk assessors.

5.3 Risk profiles and quantitative approaches in MRA

A scientific-structured MRA often needs a large number of data and time. However, this fact mainly depends on the complexity of the questions proposed and the degree of certainty required. If the question is simple (such as establishing a risk ranking for different food matrices and microbiological risks) a point-estimate approach will suffice (Ross & Sumner, 2002).

To better understand the MRA process, the Australian Food Safety Centre of Excellence developed a semi-quantitative spreadsheet (Risk Ranger) in which the user can introduce some information organized in three modules:

A. Susceptibility of the host and severity of the hazard.
B. Probability of exposure to contaminated food.
C. Probability that a given food contains an infectious dose.

As a result, the spreadsheet calculates the risk ranking derived from the inputs introduced within each item (A-C) ranging from 0 (low risk) to 100 (high risk). Later on, the tool was applied to selected food commodities like seafood (Sumner & Ross, 2002) or meat products (Sumner et al., 2005).

Risk ranking tools were further developed by the US-FDA (US-FDA, 2009), which has been recently working on fresh produce commodities. A semi-quantitative tool was created to identify priority pathogen-produce commodity combinations based on explicit data-driven risk criteria. The epidemiological information available was used to prioritize risk combinations in four dimensions: strength of the epidemiological association between the pathogen and the commodity; severity of disease; pathogen characteristics that affect disease, risk or severity; and food characteristics that affect pathogen prevalence, pathogen behavior, and likelihood of exposure by the consumers.

The main results of the model revealed that the combination leafy greens-enterohemorrhagic *Escherichia coli* O157:H7 (EHEC) consistently ranked first, followed by tomatoes–*Salmonella enterica*.

The New Zealand Food Safety Authority (NZFSA) has focused on the development of risk profiles in soft cheeses for *Listeria monocytogenes* (NZFSA, 2005a). The purpose of a risk profile is to provide contextual and background information relevant to a food/hazard combination so that risk managers can make decisions and, if necessary, take further action. In this document, MRA was conducted based on epidemiologic information, prevalence and concentration of pathogens, consumption data and dose-response relationships. A similar approach was performed for *L. monocytogenes* in ready-to-eat (RTE) salads (NZFSA, 2005b). Risk profiles have been also determined for pork and poultry products (Mataragas et al., 2008). According to Codex Alimentarius (CAC, 2007), the main information to be included in a risk profile should cover these aspects:

- Define the food-pathogen combinations that could be more important to be investigated.
- Description of the public health concern (biological hazard, illness symptoms, epidemiology of the disease, economical costs etc.).
- Production, dispatch and consumption of foods (a formal description of the farm-to-fork chain, a summary of the risk management measures and their efficacy on the food production control etc.).

- Risk assessment needs and questions for risk assessors.
- Available information and data gaps (include other previous related MRA and additional information sources to be considered in the new MRA).

A simplified deterministic MRA was addressed by Evers & Chardon (2010) for all combinations of *Campylobacter* spp. and *Salmonella* spp. with chicken fillet, filet americain (raw minced beef with mayonnaise) and table eggs in order to compare the magnitude of risks associated to each combination. The predicted risk was highest for *Salmonella* spp. in table eggs and *Campylobacter* spp. in chicken fillet. These kinds of instruments can assist to quickly determine the relative risks associated to specific food hazards, thus making decisions more efficiently. Nevertheless, when applying a simplified model, the resulting public health risk in terms of number of human cases must be interpreted in a relative sense, that is, comparing it with a reference study or other simplified pathogen–product calculations. It is advisable not to use simplified models when trying to produce an estimation of the number of cases due to the ingestion of a pathogen present in a food.

When economics is taken into consideration, a cost-utility analysis can be performed (Mangen et al., 2007). In this way, quantitative risk assessments have the additional advantage of being able to model the effects of different interventions and their associated costs.

Inclusion of variability and uncertainty in quantitative risk assessments is crucial for a more accurate determination and interpretation of risk outputs. Despite this, it should be highlighted that estimation of uncertainty is, in many cases, very difficult or even impossible when the model is complex and when a notorious lack of data is detected.

One of the earliest quantitative MRA performed at international scale was published by FAO/WHO (2002b,) which proposed MRA of *Salmonella* spp. in egg and broiler chickens. The main observations in broiler chickens were that a 50 % reduction in prevalence of contaminated flocks influenced the reduction in the final risk of *Salmonella* spp. per serving until reaching 99.75 % risk reduction. Another MRA was extended to *Campylobacter* spp. in broiler chickens and *Vibrio parahaemolyticus* and *V. vulnificus* in shellfish (FAO/WHO, 2002c).

The risk assessment developed in 2003 by the US-FDA and the Food Safety Inspection Service (FSIS) regarding *Listeria monocytogenes* in different Ready-to-Eat food categories, identified deli meats as the most risky products in relation to food-borne listeriosis in the USA. It is interesting to note that high population risks can be related to consumption of high-risk foods (e.g. pâté and meat spreads) but also to high consumption of foods with relatively low risks per serving (e.g. pasteurized milk).

FAO/WHO (2004) has also performed a MRA for *L. monocytogenes* in RTE foods: ice cream, fermented meats, cold-smoked and vacuum-packed fish. Risk estimates ranged from 1 case per 20 million servings for smoked fish to 0.4 cases per 1 million servings for fermented meats. An important finding of the risk assessment was that, based on the predictions of the models developed, nearly all cases of listeriosis resulted from the consumption of high numbers of the pathogen. Conversely, the models predicted that the consumption of low numbers of *L. monocytogenes* had a low probability of causing illness.

Risk estimation of *Salmonella enteritidis* in shell eggs and *Salmonella* spp. in egg products (liquid pasteurized egg) was performed by USDA-FSIS in two different MRA (USDA-FSIS, 1998; USDA-FSIS, 2005). Pasteurization was predicted to be effective for reducing illnesses from *S. enteritidis* in shell eggs and from *Salmonella* spp. in egg products. If all eggs produced in the US were pasteurized for 3 $\log_{10}$ units reduction of *S. enteritidis*, the annual number of

illnesses would be reduced from 130,000 to 41,000 cases. Also, if all liquid egg products produced in the US were pasteurized for 6 $\log_{10}$ units reduction of *Salmonella*, the annual number of illnesses would be reduced from 5,500 to 3,200 cases. Finally, storage time, temperature, initial levels of *Salmonella* in unpasteurized egg products and the way in which products are prepared for consumption, had the greatest impact on human health in the risk assessment of *Salmonella* spp. in egg products.

As explained above, the more complex the MRA is, the less understandable for risk managers, probably leading to misinterpretation and wrong decision-making. Nevertheless, MRA was mainly addressed to include a more extensive analysis of risk factors and to assess the effectiveness of potential management strategies to reduce microbial risks. One of the most representative examples is the MRA developed by Ross et al. (2009) for *L. monocytogenes* in RTE meats. The predictions obtained were based on data describing initial contamination levels of both lactic acid bacteria and *L. monocytogenes*, product formulation, times and temperatures of distribution and storage prior to consumption, and consumption patterns. The risk output indicated that processed meats could be responsible for up to ~40% of cases of listeriosis in Australia, a level that could be in line with the available epidemiological data. Application of risk management measures for *L. monocytogenes* in ready-to-eat lettuce salads was made by Carrasco et al. (2010). They showed that the most effective measures to reduce the risk of listeriosis were the use of specific mixture of gases in packages, the reduction of shelf-life to four days and the prevention of high-risk population from consuming ready-to-eat lettuce salads. Other methodologies are based on the implementation of advanced sensitivity techniques in MRA (Pérez-Rodríguez et al., 2007). This latter study revealed that the extremes at the right side of the dose distribution (9 to 11.5 log cfu per serving at consumption) were responsible for most of the cases of listeriosis simulated. Other approaches developed for *L. monocytogenes* in RTE meats (Mataragas et al., 2010) propose different strategies to be considered by risk managers. They applied a structured methodology using risk-based metrics such as Food Safety Objectives (FSO), Performance Objectives (PO) and Process Criteria (PC) defined by the International Commission of Microbiological Specifications for Foods (ICMSF) (ICMSF, 2002) (see Section 7 for more details). They demonstrated that by extracting useful information from a risk assessment model, practical risk management strategies and intervention steps can be developed for reducing the number of cases. Further approaches should be addressed to implement these risk-based metrics into HACCP systems.

6. Variability and uncertainty in the propagation of risks throughout the food chain

6.1 Considering variability and uncertainty for food risk management

There may be different approaches to carrying out a quantitative risk assessment. In essence, the process can be addressed from two different approaches: point-estimate and probabilistic. The first approach concerns the use of point-estimate values to describe variables of the model (Øvreberg et al., 1992). In the second approach, variables are distributions of probability which describe uncertainty and/or variability of inputs. Both approaches support adequate decisions in decision-making processes; however, by including variability and uncertainty, insight into the level of accuracy is gained. An increasing number of probabilistic risk assessments studies have been observed during the last few years for microbial and chemical hazards (Pérez-Rodríguez et al., 2007; Fairbrother

et al., 2007; Tressou et al., 2004; US-FDA et al., 2003). Although the concepts of variability and uncertainty may be easily confused, they remain distinct in a decision-making context (National Research Council [NRC], 1994). *Variability refers to temporal, spatial or inter-individual differences (heterogeneity) in the value of an input* (Cullen & Frey, 1999). For example, variability might refer to differences in the body weights between individuals, or in the consumption of specific dietary items of those individuals. In general, variability cannot be reduced by additional study or measurement. The existence of variability in the population implies that a single action or strategy may not emerge as optimal for each of the individuals, and consequently any decision made will go too far for some and not far enough for others. Uncertainty differs significantly from variability. *Uncertainty may be thought of as a measure of the incompleteness of one´s knowledge or information about an unknown quantity whose true value could be established if a perfect measuring device were available* (Cullen & Frey, 1999). Uncertainty arises from our lack of perfect knowledge, and it may be related to the model used to characterize the risk, the parameters used to provide values for the model, or both. In some cases, we can reduce uncertainty by obtaining better information, but this may not always be possible. Uncertainty implies that we might make a non-optimal choice because we may expect one outcome but something quite different might actually occur.

6.2 Propagation of variability and uncertainty in risk assessment

Uncertainty can be originated from a number of sources which may go from specification of the problem, formulation of conceptual and computational models, estimation of input values and calculation, interpretation, and documentation of the results. However, only input values may be quantified with variance propagation techniques. Uncertainty coming from the model structure, erroneous assumptions or misspecification of the model can only be analyzed by decision trees based on expert elicitation (Vose, 2000; WHO, 1995).

Variability is a result of the natural variation of the observed system. This may be spatial, temporal or inter-individual variation. Examples of this may be the distribution of a certain hazard in a specific food batch (i.e. special variation) or between different batches over time (i.e. temporal variation). Variability also exists between and within strains in the microbial response (e.g. growth, death, or survival) to environmental conditions (e.g. temperature, pH, etc.), which is named biological variability. In some cases, there may be several subpopulations which are more nearly homogenous than the overall population. In such cases, the observed variability may be well described by a mixture of frequency distributions for various subpopulations (Cullen & Frey, 1999). Both variability and uncertainty may be quantified using distributions. However, the interpretation of the distributions differs in each case. Usually, variability is represented as distributions of frequencies which provide the relative frequency of values in a specific interval. In turn, uncertainty probability distributions reflect the degree of belief, or subjective probability that a known value is within a specified interval. Figure 2 shows the uncertainty and variability of a hypothetical variable.

The most used techniques to propagate uncertainty and variability in a probabilistic food risk assessment model comprises classic statistics and numerical methods (Vose, 2000). The method of moments is a classical method that can be applied to propagate information regarding uncertainty and variability based on the properties of mean and standard deviation of input values. However, this method is only valid when input values are distributed normally. By contrast, algebraic methods can be applied even when other types

of distributions than the normal distribution are used to characterize uncertainty and variability; this method, though, is limited to specific distributions which are not usually used in risk assessment studies. The Monte Carlo analysis is a numerical method which allows propagating numerous types of probability distributions in risk assessment studies based on the random sampling processes of each distribution. This method has become quite popular among food risk assessors and managers as the existence of commercial software enables easy application by users who are not advanced practitioners in numerical methods.

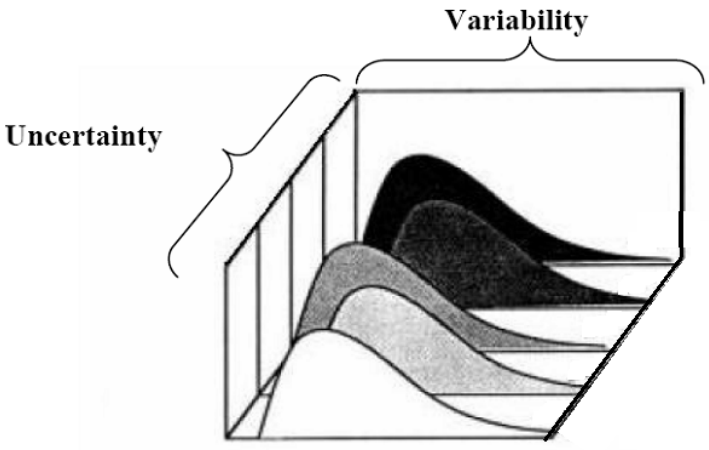

Fig. 2. Representation of variability and uncertainty for a hypothetical variable. Adapted from Hoffman & Hammonds (1994).

Although the specification of distributions for all or most variables in a Monte Carlo analysis is useful for exploring and characterizing the full range of variability and uncertainty, sometimes it is unnecessary and not cost-effective. The study by Pérez-Rodríguez et al. (2007) pointed out that certain inputs (e.g. serving size) in MRA studies might be described by point-estimate values provided they are not significant sources of uncertainty or variability within the risk estimate. Similarly, Leeuwen & Hermens (1995) stated for chemical hazards that the results of simple model calculations are easier to communicate and, therefore, may serve to better support the decision. In conclusion, uncertainty and variability components should be applied when necessary, and a previous analysis should be carried out by risk assessors in order to determine which inputs are more relevant as uncertainty and variability sources in the risk estimate. Based on results, simpler models could be better understood and applied by food risk managers to make decisions.

6.3 Separation of variability and uncertainty improves food Risk Management

Variability and uncertainty have different ramifications in the decision-making process. By confronting variability and uncertainty, risk managers can better understand how variability affects the distributions of exposure or risk, the impact of various assumptions, data gaps or model structures on decision-making. Uncertainty forces decision-makers to judge how probable it is that risk will be overestimated or underestimated for every

member of the exposed population, whereas variability forces them to deal with the certainty that different individuals will be subjected to risks both above and below any reference point chosen. Some studies have demonstrated how better characterization of variability and uncertainty in the risk assessment may lead not only to better risk management, but also to better risk communication (Pérez-Rodríguez et al., 2007). In exposure assessment of food hazards, the common source of variability resides in the different characteristics between individuals (e.g. intake rates, activity patterns, geographical distribution) and/or the spatial and temporal distribution of contaminants in foods. However, uncertainty could be present in such characteristics or in the contamination distribution, for example, due to measurement errors or sampling of lots. In these cases, the resultant variability distribution would also be uncertain. Inference to the whole population from the observed distribution could lead to uncertainty; hence the contaminant distribution may account for both uncertainty and variability. However, sometimes, separation between both uncertainty and variability is not clear. In these cases, the final decision about which part of the input corresponds to uncertainty and variability will depend on the interpretation made by the risk assessor or manager.

Considering separately both components can be crucial to better guide risk managers in the decision-making process thereby resulting in more adequate food policies. Understanding variability can help to identify significant subpopulations which are more relevant to risk. Uncertainty in the observed values for specific characteristics or parameters can be used to elucidate whether further research or alternative methods are needed to reduce uncertainty.

7. Risk management metrics

7.1 Appropriate Level of Protection (ALOP)

The SPS Agreement (WTO, 1995) states that Members States are autonomous to adopt SPS measures to achieve their health protection level. This level, called Appropriate Level of Protection (ALOP) is defined as "*The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory*." An ALOP represents the current public health status and not a goal to be achieved in the future. The ALOP is strongly influenced by aspects such as the capacity of the consumer to control it, the severity of the hazard, and level of alertness among consumers raised by the hazard. In short, ALOP choice greatly depends on the perception of the risk with regard to the hazard and food associated. This concept has been incorporated by organizations like FAO and ICMSF as a basis to develop a new global risk management schemes. FAO/WHO (2002a, 2006b) and CAC (2007) develop in more detail the role of the ALOP in a formalized and global process of Microbiological Risk Management. According to FAO/WHO (2002a), an ALOP is specified as a statement of the impact of the illness (e.g. number of cases/100,000 population/year) associated with a hazard-specific food product combination in a country, it being common to frame it in a context of continuous improvement in relation to the reduction of the illness.

The ALOP is usually expressed as the impact level of an illness in the population (e.g. annual number of cases). Nevertheless, Havelaar et al. (2004) proposed the use of integrated public health measures. Specifically, they proposed the index "Disability Adjusted Life-Year" (DALY), which has been considered by WHO (2008) as the basis for the establishment of public health goals for the quality of drinking-water (Havelaar & Melse, n.d.). Such a proposal is based on the fact that the ALOP expressed as impact does not seem to be

appropriate to represent illnesses associated with a microbial hazard of multiple nature (e.g. gastroenteritis, syndrome of Guillain-Barré, reactive arthritis and mortality caused by *Campylobacter spp. ,Campylobacter thermophilus*) (Havelaar et al., 2004). Other decisions such as the distinction between different population groups (e.g. high risk populations), the selection of one or more foods as vehicles of hazards for ALOP establishment, or the inclusion of other ways of transmission (e.g. from person to person or from water to person), etc., still have to be discussed for a better application of the ALOP.

Determining the ALOP may be considered a complex task. Information from health surveillance systems is crucial to undertake the ALOP determination. However, the confirmed-cases reported by surveillance systems represent only a small fraction of the total disease incidence, and additional information should be applied to calibrate the so-called surveillance pyramid. The sensitivity of the surveillance may be another important factor to be considered since this can vary between countries and within one country over time. Because most food-borne pathogens can also be transmitted by other routes (e.g. the environment or direct contact with animals), it is also necessary to establish the fraction of all cases that is attributable to food, and within food categories which food types are associated with exposure. For that purpose, information from various sources such as outbreak studies, analytical epidemiology, microbial subtyping and risk assessment can be applied; this process is called source attribution (Batz et al., 2005). FAO/WHO (2006b) pointed out that Microbiological Risk Assessment can contribute, in a fundamental way, to an elucidation of the ALOP.

7.2 Public health goal

The public health goal concept, different from ALOP, is intended to derive strategies to improve the future public health status and reduce disease burden (FAO/WHO, 2006b). Public health goals are usually set by government or public health bodies, with a varying degree of input from stakeholders, and imply some consideration of the current health status and disease burden (in the population as a whole or in vulnerable sub-populations). In setting goals, consideration may also be given to possible interventions and how achievement of the goal is to be measured. The public health goal can be specified following two approaches. Establishing an objective of reduction of illness (e.g. from 10 to 5 in the rate of population/year) assuming that the objective is feasible; or else, modifying such objectives as function of management capacities. Both approaches have strengths as well as weaknesses. For example, in the first case, more resources are destined to management, offering greater flexibility and promoting innovation, although it is more probable that the objective is unrealistic and impossible to be achieved. On the other hand, the second approach, based on the actual technical status, is more likely to succeed in achieving the goal. Nevertheless, for this, the industry has to accomplish technological requirements and/or adapt methods to help reach the objective of public health.

7.3 Food safety objective (FSO)

The ALOP is not the most adequate concept for developing and implanting the necessary control measurements throughout the food chain (Havelaar et al., 2004). The terms in which the ALOP is expressed do not form part of the "language" that the industry or other operators of the food chain use for food safety management (Gorris, 2005). Therefore, the creation of a new concept was proposed (ICMSF, 2002), i.e. Food Safety Objective (FSO), which aims to establish a link between the ALOP and the "hazard" status of a food at the time of consumption.

The ICMSF (2002) defined FSO as "The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the ALOP". The FSO allows a high level of flexibility to design and implement control measurements throughout the food chain (Zwietering, 2005).
FSO differs from microbiological criteria. FSO is the hazard level providing an ALOP, and specifies a goal which can be incorporated into the design of control measurements in the food chain (van Schothorst, 2005). In turn, microbiological criteria are used to verify analytically the acceptance of a batch or a group of batches. Besides, microbiological criteria may be established for quality as well as safety concerns (CAC, 2003).

7.4 FSO in the framework of microbiological food safety risk management

According to CAC (2008), FSO could be well established on the basis of epidemical data which describe the current status of public health for a hazard or by the application of a Risk Characterization curve. In the latter case, the curve relates FSO with an ALOP (ICMSF, 2002), the FSO being linked to a quantitative risk assessment in which variables can be related to the FSO and finally to an ALOP. Nevertheless, the literature is not clear about the consideration of the ALOP in order to establish an FSO. In practice, an FSO could be established without using an ALOP. As a matter of fact, microbiological criteria and other control measures have been raised through history mainly based on decisions of experts' panels. Nevertheless, firstly, it should be considered whether an FSO is feasible or not, and if the food business operators have the means to fulfill it.
Risk Management systems based on the FSO may be structured in five fundamental facts according to Swarte & Donker (2005): risk assessment; establishment of an ALOP and FSO; translating the risk management to processes of management; interaction between risk assessment and risk management ; and start of a new cycle or consolidation
The ICMSF (2002) does not specify the way of application of the Risk Characterization curve, since it does not address how, by means of a dose–response model (hazard characterization), an FSO value can be estimated from a value of the impact of the illness in the population (ALOP). We should keep in mind that a dose-response model deals with individual risk (individual probability of getting ill) and not population risk (e.g. number of cases/100.000 population).
The FSO can be understood as a more or less complex system of "quantifiable" objectives that food business operators use as a criterion to select and develop the most adequate control measures. To achieve an FSO, the ICMSF (2002) and CAC (2008) have proposed different concepts to be applied throughout the food chain:

- Performance Objective: "*The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable*".
- Performance Criteria: "*The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a Performance Objective or an FSO*".

These terms and concepts must again be translated to others that food operators may understand, i.e. process criteria and product criteria. Van Schothorst (2002) defined process criteria as the control parameters (e.g. time, temperature, etc.) at a step that may be applied to reach efficiency criteria. In a HACCP context, these would correspond with the control limits of a process (Jouve, 1999). Product criteria (e.g. pH, water activity, etc.) are defined as the parameters of a food product which are essential to assure that an FSO will be reached

(van Schothorst, 2002, 2005). This set of objectives, criteria and limits can be considered in HACCP systems and Good Manufacture Practice/Good Hygiene Practice guides to finally achieve an FSO (van Schothorst, 2005).
ICMSF (2002) proposed an inequation which considers the effect of different processes and subprocesses in the food chain (growth, inactivation, etc.) to reach an FSO:

$$H_0 + \sum I + \sum R \leq FSO \quad (1)$$

where H_o is the initial population of microorganisms, I is a factor of increase and R is a factor of reduction. All terms are expressed in $\log_{10}$.
For validation of control measures in a food chain, the FSO concept can be used to structurally combine the initial level, reduction and increase of contaminants. The impact of taking into consideration both the level and the variability of these factors on the proportion of product meeting the FSO has been investigated by Zwietering et al. (2010), working out whereabouts in the process the main factors are found to control the proportion of product meeting the FSO.
Verification of activities into Food Safety Management system based on the ALOP/FSO and other related management metrics can be performed by using information from epidemiological surveillance systems (Walls & Buchanan, 2005). In some cases a public health goal may not be reached because the factors considered in risk assessment (basis to establish the FSO) have changed or because other important factors have not been included in risk assessment. Verification process should be considered as crucial after the implementation of Food Safety Management systems. Verification process would permit discernment between those changes in public health status produced by the implementation of FSO and those due to natural fluctuations. Currently, FAO is working on the elaboration of guidelines for the validation process of food hygiene control measures (FAO/WHO, 2006b).

8. Future and prospective research

Efforts are continuously being made to improve food safety in consonance with modern technologies. Intelligent packaging or labels are examples of the most recent advances in the food safety field. Genomics and proteomics are disciplines which are being increasingly applied in food safety in order to explain microorganism behavior, such as the virulence of different strains, adaptability to environmental conditions or *quorum sensing*. In this line, the biotechnology industry has benefitted from a major development of biosensors able to, for example, detect virulence genes in pathogens.
Food safety risk management at the food industry level has evolved from final product testing to risk prevention by application of HACCP systems. However, the development of non-destructive technology, such as image analysis, near infrared spectroscopy or radio frequency identification tags, may bring back final product testing, which should require the adaption of the management systems currently implemented.
Just as quantitative risk assessment is preferred for providing more information, HACCP systems could also include quantification of the different processes, i.e. how and to which extent different process affect hazards. In this way, HACCP would be "connected" to risk management based on risk assessment and with health official control, which increasingly demand quantitative justification for different practices and processes.

The continuous development of alternative food standards, specifications, formulations and novel foods, together with increasing international trade, would require more sophisticated risk management measures. Jacxsens et al. (2009) proposed the implementation of microbial assessment schemes as a tool for the (yearly) verification of a food safety management system in food industries, as required by CAC (2003). The structure of these kind of system is susceptible to be in share among food enterprises to identify and agree on microbiological safety issues and risk management measures.

Environmental sustainability of food production is also an important issue to be considered when managing food risks. A way of evaluating the environmental impact of a certain product, process or related activity is through the so-called *Life cycle assessment* (Roy et al., 2009). *Life cycle assessment* is a tool for evaluating environmental effects of a product, process, or activity throughout its life cycle or lifetime, which is known as a 'from cradle to grave' analysis. Environmental awareness influences the way in which legislative bodies such as governments, will guide the future development of agricultural and industrial food production systems. A collaborative framework should be established by risk assessors and managers, food business operators and governmental authorities to couple life cycle assessment with risk management based on risk assessment. International standardization on how to use these tools would broaden their practical applications, improve the food safety and reduce human health risk.

9. Acknowledgments

CTS-3620 Project of Excellence from the Andalusia Government, AGL 2008-03298/ALI project from the Spanish government, FP7-KBBE-2007-2A nº 222738 project from the VII Framework Programme and European ERDF funding are greatly acknowledged for providing material and specially human resources, making possible the continuation of risk assessment and management activities at national and European level by our research group AGR170 "HIBRO".

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Risk Management in Environment, Production and Economy
Edited by Dr. Matteo Savino

ISBN 978-953-307-313-2
Hard cover, 214 pages
Publisher InTech
Published online 12, September, 2011
Published in print edition September, 2011

The term "risk" is very often associated with negative meanings. However, in most cases, many opportunities can present themselves to deal with the events and to develop new solutions which can convert a possible danger to an unforeseen, positive event. This book is a structured collection of papers dealing with the subject and stressing the importance of a relevant issue such as risk management. The aim is to present the problem in various fields of application of risk management theories, highlighting the approaches which can be found in literature.

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